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46. (Once amended) A composition comprising:

(a) biologically active insulin-like growth factor-1 (IGF-I) or biologically active analogue thereof having an amino acid sequence that shares at least 70% sequence identity with the amino acid sequence for human IGF-I, wherein said IGF-I or analogue thereof is present at a concentration of at least about 12 mg/ml when said composition is at a temperature of about 4°C;

- (b) a solubilizing compound selected from the group consisting of arginine, N-acetyl-arginine, a dipeptide containing arginine, a tripeptide containing arginine, and guanidine hydrochloride, wherein said dipeptide or said tripeptide increases solubility of said IGF-I or analogue thereof at a pH of at least about 5.5; and
- (c) a buffer such that the composition has a pH of about pH 5.5 to about pH 9.0.

REMARKS

Claims 31 and 46 have been amended. Support for amendments to the claims can be found throughout the specification and in the original claims. No new matter has been added by amendment.

Specifically, claims 31 and 46 have been amended to include N-acetyl-arginine, a dipeptide containing arginine, and a tripeptide containing arginine as solubilizing compounds for purposes of clarifying the term "arginine analogue." The dipeptide or tripeptide in these compositions contains arginine and must increase solubility of IGF-I or analogue thereof at a pH of at least about 5.5 such that the claimed IGF-I compositions have an IGF-I concentration of at least about 12 mg/ml under the recited pH and temperature conditions. Support for the amendments to these claims resides in the specification, for example, at page 7, lines 21-25, at page 17, Example 3, and in Figure 3.

Claims 29-48 and 85-112 are pending. Reexamination and reconsideration in view of the amendments and remarks are requested. The Examiner's remarks in the Official Action are addressed below in the order set forth therein.